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10/767,752	01/29/2004	Carol A. Tosaya	D-02017B1	5700

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EXAMINER

KISH, JAMES M

ART UNIT	PAPER NUMBER
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3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/767,752	Applicant(s) TOSAYA ET AL.	
	Examiner JAMES KISH	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it contains legal phraseology, such as "means" language. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 12-13, 16-17, 21-22, 24, 35-49, 54-55, 57-58, 63-64 68-70, 77, 82-83, 92-94, 97 and 100 are objected to because of the following informalities:

Regarding claims 12-13, 16, 22, 24, 55, 63-64 and 82, it is unclear of the emitter stated in these claims relates to, if at all, to the emitter in claim 1.

Regarding claims 17, 21 and 24(d), these claims recite functional language and do not provide, nor has any provision been shown previously, a structural aspect capable of producing this outcome.

Claim 35 states the use of at least one of a drug, medicament, vitamin, mineral or controlled dietary matter or content is utilized, employed, or is an anti-inflammatory. Independent claim 1 states that a drug is optional. It is unclear as to whether a "drug, medicament, vitamin, mineral or controlled dietary matter or content" in Claim 35 is the optional drug or a different, required drug. Furthermore, if these are referring to the same optional drug of Claim 1, then Claim 35 is improper for being broader than the claim from which it depends. Similar occurrences can be found in claims 36-49, 54, 68-

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70. As well as claim 92-94, which dependent from claim 91. The Applicant is requested to use consistent language throughout the claims.

Claim 39 states, "either unaided or in aided form, wherein said aid comprises one of:" Therefore, options (a), (b), (c), (d) and (e) are irrelevant since the one drug, medicament, vitamin, mineral or ingested dietary content reaches a brain or neurological region by passing through the BBB unaided.

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 49 provides for acoustic or vibratory exposure to allow therapy "without the required use of a drug..." Therefore, if the use is not required it is optional, which is already provided in Claim 1.

Regarding claims 57-58, these claims fail to further limit the subject matter of previous claim 56. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The Examiner believes claim 77 should read, "The system of claim 1, wherein -- at least one of--:"

Claim 82 states, "wherein said at least one acoustic emitter is inside ... and said acoustic or vibratory energy emanates..." It is unclear whether the Applicant intended to positively claim the emitter as an acoustic emitter as opposed to an "emitter means to deliver acoustic, ultrasonic or vibratory energy", which is the claim language of

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independent claim 1. The Applicant is requested to use consistent language throughout the claims.

Claim 83 states, "wherein any emitter energy beam-forming or beam-steering is done at least for the purpose of..." First of all, this is an intended use, solely giving reasoning for beam-forming or beam-steering. Secondly, there is no recitation in claim 83 or in claim 1 that provides for beam-forming or beam-steering.

Claims 94 and 97 are indicated as system claims. However, these claims depend from a method claim.

Claim 100 states, "administration of acoustic or vibrational energy." The subsequent method steps (i), (ii), (iii), and (iv) all call strictly for acoustically enhancing or enabling. The Applicant is requested to use consistent language throughout the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-8, 12-13, 24 and 65 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 7-8, 12-13 and 24 define structure with respect to the patient.

Certain aspects of claim 65 are directly claiming a shaved human head and/or wetted hair. This is directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-21, 24-51, 55-58, 61-74, 76-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the emitter means known to the inventor and described in the disclosure, does not reasonably provide enablement for all conceivable means capable of emitting. As claim 1 recites nothing more than a single emitter means. Furthermore, the remainder of the above cited claims fails to set forth any further structural limitations. These claims are deemed to encompass a scope of undue breadth, which has previously been held as deficient under 35 U.S.C. 112 (*In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983)).

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 32, 52-54, 65, 75 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 states at line 3, "is diagnosed to *possibly, likely or certainly be one or more of...*" It is recommended this language be changed to, for example, -- is at least one of: --

Claim 83 does not positively claim beam-forming or beam-steering. A claim must distinctly point out what is patentable matter.

Regarding claims 1 and 52-54, the word "means" is preceded by the word(s) "emitter" in claim 1 and "cooling or heat-exchange" in claims 52-54 in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Further regarding claim 1, the recitation of the limitation "the emitter" in line 13 lacks antecedent basis due to the improper invoking of 112, 6th paragraph of the emitter means in part (a).

Claim 65 recites the limitation "said acoustic or vibratory coupling means." There is insufficient antecedent basis for this limitation in the claim.

Claim 75 recites the limitation "the therapy delivery means." There is insufficient antecedent basis for this limitation in the claims. Furthermore, it appears the Applicant is attempting to invoke 112, 6th paragraph. The terminology "means for" or "step for" is the proper format for invoking 112, 6th paragraph.

Examiner's Note

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Regarding claims 2-6, 9-11, 26, 29-34, 36-41, 45-51, 61-62, 67-75, 78-79 and 83-90, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use then it meets the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 11, 16-21, 25-32, 35-37, 42-43, 49-51, 54-61, 63, 65-66, 71, 76-78, 81, 83-85 and 89 are rejected under 35 U.S.C. 102(e) as being anticipated by Bystritsky (US Patent No. 7,283,861). Bystritsky discloses a system and corresponding method for modifying electrical currents in brain circuits through the simultaneous use of focused ultrasound pulse (FUP) and existing brain imaging systems. The invention is used for research treatment and diagnosis of neurological disorders whose biological mechanisms include brain circuits (see Abstract). Bystritsky's system utilizes a cap that fits on the head of a patient that comprises ultrasonic emitters for sending FUP into the patient's brain (see Figures 1-3). Among other disorders this can be used for are

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Parkinsonian Disease, Huntington Chorea, La Touretts and tick syndromes (column 1, lines 25-45). The FUP can be focused to any location(s) in the brain and can account for bone density and structure of the skull and brain (column 4, lines 25-34). Repeated use of the methods disclosed by Bystritsky can cause long-term or permanent changes to the [brain] circuits (column 4, lines 45-59). This can be used to aid in the recovery, growth, regrowth, new growth or improved physical, biological and cognitive functionality of brain-related or neurological-related cells, or functional pathways negatively impacted or stressed by deposits, nodules or bodies. The methods may be used without additional agents, but may also be used concurrently with pharmaceutical agents (column 5, lines 21-32).

Regarding independent claim 1, portions (b), (c), and (d) are intended uses of the apparatus. The only portion of the claim that provides structural limitations to the apparatus is "(a) emitter means to deliver acoustic, ultrasonic or vibratory energy."

Regarding claims 29-31, these claims are method steps and do not limit the structure from which these claims ultimately dependent.

Regarding claim 36, the fact that acoustic or vibratory therapy exposure effects the action of the drug is not a structural limitation, but rather is a property based on the drug, medicament, vitamin, etc., that is given to the patient. Bystritsky is capable of enhancing the effects of certain drug, medicament, vitamin, etc., that would be given to the patient if the drugs are effected by ultrasound.

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Regarding claim 65, if a patient is bald and the procedure of Bytritsky is performed, a patient with reduced hair quantity will have the device coupled to him/herself.

Regarding claims 1, 35-48 and 54, the system is claimed to function with the option of a drug. Since this is not necessary for the system, Bystritsky's methods and system cover these optional limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-6, 10, 12-15, 22-24, 32-34, 35, 38-41, 44-48, 52-54, 62, 64, 67-75, 78-79-80, 82, 84-88, 90-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent No. 7,286,879) in view of Shalev et al. (US Patent Pub. No 2003/0176892). Wallace discloses a method of treating a neurological disorder in a patient. The method comprises introducing a stimulation lead within a patient's head, advancing the stimulation lead within an intracranial vascular body, placing the stimulation lead adjacent the fastigium nucleus of the patient's brain and stimulating the fastigium nucleus with the stimulation lead to treat the neurological disorder (see Abstract). Wallace states that this method can also be used to treat Alzheimer's patients by increasing the blood flow within the brain in order to help metabolize amyloid plaque (column 7, lines 27-29). However, Wallace uses electrical stimulation and fails to provide emitters that use acoustic, ultrasonic or vibratory stimulation. In a similar field of endeavor, Shalev teaches a method and apparatus for stimulating the sphenopalatine ganglion to modify properties of the blood-brain barrier (BBB) and cerebral blood flow (paragraphs 36-41). Shalev utilizes, among other possibilities, mechanical vibration or ultrasonic transmissions as stimulation means (paragraph 68). Also provided at paragraph 43, Shalev states that the invention provides improved methods for treating neurological diseases (for example, Alzheimer's disease). Methods of stimulation are described as electrical, however, mechanical vibration and ultrasonic transmission are both contemplated (paragraph 68). Furthermore, US Patent No. 5,756,071, issued to Jolesz et al., is incorporated by reference into the disclosure of Shalev. Jolesz uses ultrasound in conjunction with MRI to open a portion of the BBB

(paragraph 15). A temperature transducer is used in Shalev to monitor the effect of the stimulation applied (paragraph 156).

Regarding independent claim 1, portions (b), (c), and (d) are intended uses of the apparatus. The only portion of the claim that provides structural limitations to the apparatus is "(a) emitter means to deliver acoustic, ultrasonic or vibratory energy."

Regarding claims 45 and 46, these claims are purely functional and do not provide patentable limitations for the system.

Regarding claims 1, 35-48, 54 and 87, the use of a drug is optional. Since this is not necessary for the system, Wallace and Shalev's methods and system cover these optional limitations.

Regarding claims 95-97, Shalev incorporates Jolesz by reference. Thereby providing the teachings of another method to open the BBB in which ultrasound is utilized. The ultrasound energy overlaps in Jolesz. These claim limitations are taught in the patent granted to Jolesz and are therefore taught within the disclosure of Shalev.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JMK